

Final Report The Birth Defect Prevention Act of 1984

A Report to the Legislature



**California Environmental Protection Agency
DEPARTMENT OF PESTICIDE REGULATION**

July 2001

California Environmental Protection Agency
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Gray Davis, Governor

Winston H. Hickox, Secretary
California Environmental Protection Agency

Paul E. Helliker, Director
Department of Pesticide Regulation

This report's executive summary is available on DPR's Web site at
<<http://www.cdpr.ca.gov>>.

EXECUTIVE SUMMARY

June 2001 Report to the Legislature

PURPOSE:

This report presents the status of the chronic health effects studies required by the Birth Defect Prevention Act (the Act) for the priority 200 active ingredients. The Department of Pesticide Regulation (DPR) identified these active ingredients in 1985 as having the most significant data gaps, widespread use, and which were suspected of being hazardous to people. For the priority 200 active ingredients, the chronic health effects studies were due to DPR by March 30, 1996. If pesticide registrants failed to submit the required studies, data gaps exist. A data gap means that DPR lacks adequate health effects studies in any of the following areas: chronic toxicity, mutagenicity, neurotoxicity, oncogenicity, reproductive effects, and teratology. Pesticide registrants are in compliance with the Act when DPR receives final reports for all required studies, unless later evaluation determines that any study is not adequate.

This is DPR's final report to the Legislature on the status of the health effects studies for the priority 200 active ingredients, as required by 1991 legislation (SB 550), amending the Act.

BACKGROUND:

The Act required DPR to acquire certain toxicological data for registered pesticide active ingredients in order to make a scientific determination that their continued uses will not cause significant adverse health effects. If the use of an active ingredient presents potential significant adverse effects, the Act requires DPR to suspend or cancel the registration of pesticide products containing those active ingredients.

In January 1986, DPR notified each registrant of pesticide products containing any of the priority 200 active ingredients of the data required to fill the data gaps. DPR found that much of the data submitted in response to this data call-in notice were from studies that did not meet the U.S. Environmental Protection Agency (U.S. EPA) guidelines for conducting such studies. Because these studies had been conducted some years ago, many registrants were unable to obtain additional data from the laboratories which conducted the original studies. Thus, the studies could not be upgraded. Then registrants contracted with laboratories to begin new studies; however, most registrants failed to complete and submit new chronic health effects studies within the time frames in the law.

AMENDMENTS:

The Act was significantly amended in 1991 and 1996. In 1991, amendments strengthened the Director's authority to suspend product registrations. They required the Director to initiate a suspension process for products containing active ingredients for which data gaps existed after December 31, 1991. These amendments provided that under certain conditions, registrants and others could petition for additional time to submit the data. However the law clearly states that no pesticide product shall remain registered if it contains any of the priority 200 active ingredients for which data gaps exist after March 30, 1996.

In March 1996, another amendment to the Act allowed continued registration of products containing two active ingredients while studies were being completed. For methyl bromide and pentachlorophenol, the final reports were submitted to DPR before December 31, 1997. These reports were submitted and found acceptable by DPR.

REPORT SUMMARY:

Of the priority 200 active ingredients, 145 remain subject to the data call-in. Of the 55 active ingredients that are no longer subject to the data call-in, DPR suspended registrations for eight active ingredients. Product registrations are suspended if data for any active ingredient cannot be upgraded with the submission of additional information or if data were not submitted. Of the 145 active ingredients still subject to the data call-in, none have data at DPR pending evaluation, and two are exempted from the data requirements¹.

No data gaps exist for any of the 145 active ingredients which remain subject to the data call-in.

The table summarizing the June 2001 final report follows.

¹ FAC section 13127(e) permits the Director to exempt from the data requirements products that meet specified criteria. They must have limited use and would cause substantial economic hardship if unavailable. In addition, it must be determined that no significant exposure to the public or workers would occur, and that the products are otherwise in compliance with federal law. If all products for a given active ingredient are to be exempted, the exemption is limited to three years in duration.

**BIRTH DEFECT PREVENTION ACT OF 1984
FINAL REPORT SUMMARY
JUNE 2001**

Status summary of the priority 200 pesticide active ingredients identified according to Food and Agricultural Code section 13127(a).

I. 55 active ingredients are no longer registered in California¹

II. 145 active ingredients are subject to the data call-in

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| a. | A complete set of adequate data is on file | 134 |
| b. | Adequate data exist in public literature to assess potential adverse health effects | 9 |
| c. | Active ingredient exemptions | 2 |
| | Chloroneb: one product registration suspended; one product granted FAC section 13127(e) exemption ² . | |
| | Diclofop-methyl: one product exempted from data requirements for three years under FAC section 13127(e)(2) ³ ; exemption expires on April 12, 2002. | |
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¹ Products containing eight active ingredients were suspended and have been withdrawn from registration in California. These eight active ingredients are included in the 55 "no longer registered" active ingredients.

² FAC section 13127(e) permits the Director to exempt from data requirements any product which he determines has limited use or that substantial economic hardship would result to users due to its unavailability, and that there is not significant exposure to the public or workers, and the product is otherwise in compliance with federal law. There are two products registered in California containing the active ingredient chloroneb.

³ FAC section 13127(e)(2) limits the director from exempting all pesticide products containing an active ingredient to three years duration. Because there is only one product registered in California containing the active ingredient diclofop-methyl, the three-year limit applies.